4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-0362]

A Risk-Based Approach to Monitoring of Clinical Investigations--Questions and Answers; Guidance for Industry; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the *Federal Register* of April 12, 2023. The document announced the availability of a final guidance entitled "A Risk-Based Approach to Monitoring of Clinical Investigations--Questions and Answers; Guidance for Industry." The notice of availability for this final guidance was published with an incorrect OMB control number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Mona Shing, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3355, Silver Spring, MD 20993-0002, 301-796-0910.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of April 12, 2023 (88 FR 22038), in FR Doc. 2023-07687, the following correction is made:

1. On page 22040, in the first column, in the last sentence of "II. Paperwork Reduction Act of 1995," the OMB control number 0910-0733 is corrected to read: "…and the collections of information in FDA's guidance for industry entitled "Oversight of Clinical Investigations--A Risk-Based Approach to Monitoring" have been approved under OMB control number 0910-0014." The correction changes the OMB control number from a number that was discontinued to an active one.

Dated: April 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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